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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,387	10/21/2003	Anne Marie Chalmers	AIJ-001CP	2369

959 7590 05/30/2006

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EXAMINER
TRAN, SUSAN T

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/690,387	CHALMERS, ANNE MARIE	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,8,14,26,32 and 55-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,8,14,26,32 and 55-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Wittwer et al. US 4,738,817.

Wittwer discloses a pharmaceutical capsule comprising multi subunits connected by a lamella (column 17, lines 35-43; and figs. 86-89). The subunits can be made in different shapes and with different materials (figs. 86-89 and 93; and column 18, lines 1-14).

Claims 55-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Grayson US 4,487,327.

Grayson discloses a capsule comprising a pair of cylindrical, hollow body (**16** and **18**) locked to one another by snapping together the two bodies **16** and **18** (abstract; fig. 6; column 2, lines 1-7; and column 4, lines 6-20). The bodies can also be locked to one another by a latching assembly (affixing means) (abstract; fig. 1; and column 3, lines 10-14). Grayson also discloses the capsule is filled with medicines, foods, and the like (column 1, lines 45-47).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14, 26 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wittwer et al. US 4,738,817, in view of Tanner et al. US 5,624,681 and Adusumilli et al. US 5,595,758.

Wittwer is relied upon for the reason stated above. Wittwer does not expressly teach the translucent or transparent type of capsule.

Tanner teaches a pharmaceutical capsule suitable for human ingestion comprising a transparent color neutralized nontoxic soft elastic gelatin capsule (column 1, lines 66 through column 2, lines 1-4).

Adusumilli teaches a drug delivery system comprising a translucent soft gelatin capsule (abstract; column 3, lines 43-60; and claims 1 and 13).

Thus, it would have been obvious to one of ordinary skill in the art to modify the capsule of Wittwer using the transparent or translucent gelatin capsule in view of the teachings of Tanner and Adusumilli, because Tanner teaches the use of transparent capsule permits simpler identification of altered dosage unit forms (column 2, lines 20-27), because Tanner teaches the use of transparent capsule simplifies the quality control examination of capsules (column 2, lines 45-57), because Adusumilli teaches the use of translucent capsule make it easier to detect the imperfections of the fillings inside the capsule (column 2, lines 23-29), and because Wittwer teaches the use of various gelatin compositions with the desirability to obtain temper resistant capsules (column 2, lines 29-36).

Claims 59-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grayson US 4,487,327, in view of Tanner et al. US 5,624,681 and Adusumilli et al. US 5,595,758.

Grayson is relied upon for the reason stated above. Grayson does not expressly teach the translucent or transparent type of capsule.

Tanner teaches a pharmaceutical capsule suitable for human ingestion comprising a transparent color neutralized nontoxic soft elastic gelatin capsule (column 1, lines 66 through column 2, lines 1-4).

Adusumilli teaches a drug delivery system comprising a translucent soft gelatin capsule (abstract; column 3, lines 43-60; and claims 1 and 13).

Thus, it would have been obvious to one of ordinary skill in the art to modify the capsule of Grayson using the transparent or translucent gelatin capsule in view of the teachings of Tanner and Adusumilli, because Tanner teaches the use of transparent capsule permits simpler identification of altered dosage unit forms (column 2, lines 20-27), because Tanner teaches the use of transparent capsule simplifies the quality control examination of capsules (column 2, lines 45-57), because Adusumilli teaches the use of translucent capsule make it easier to detect the imperfections of the fillings inside the capsule (column 2, lines 23-29), and because Grayson teaches the desirability to prevent accidental loss of the contents of the capsule, or tampering of the capsule (column 1, lines 6-12).

Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grayson US 4,487,327, in view of Wittwer et al. US 4,738,817.

Grayson is relied upon for the reason stated above. Grayson does not explicitly teach the third compartment (body).

Wittwer teaches a temper resistant capsule comprising multi subunits, *e.g.*, three compartments capsule that can be filled with the same or different drugs in various therapeutic dosages (column 11, lines 61 through column 12, lines 1-6; and figures 42-43 and 86-88). Thus, it would have been obvious to one of ordinary skill in the art to modify the capsule of Grayson to further comprising a third compartment/subunit in view of the teaching of Wittwer, because Wittwer teaches capsules containing a plurality of compartments for different dosage forms and having various locking means to provide a

tamper/separation resistant between the compartments (column 2, lines 32-36), because Wittwer teaches multi-compartment capsules having smooth outer surface which would render them easy to swallow and to be swallowed two or more different medicaments simultaneously (column 2, lines 64-65; column 14, lines 30-31; and column 17, lines 45-50), and because Grayson teaches capsules containing two subunits that locked together to prevent accidental loss of the contents and to prevent tampering (column 1, lines 5-11).

Response to Arguments

Applicant's arguments filed 03/10/06, with respect to the rejections of claims 1-54 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, in view of applicant's amendment filed 03/10/06, new grounds of rejection is made over Grayson, Wittwer, Tanner, and Adusumilli.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
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